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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION ONE

WINIFRED ARMSTRONG et al., Plaintiffs and Appellants, v. OPTICAL RADIATION CORPORATION, Defendant and Respondent.	B089213 (Super. Ct. No. NC008506)

APPEAL from a judgment of the Superior Court of Los Angeles County, James L. Wright, Judge. (Assigned by the Chairperson of the Judicial Council.) Reversed.

Charlotte E. Costan, Kaplan Law Corporation and Thomas D. Peterson-More for Plaintiffs and Appellants.

Kolts and Nawa and Kathlene Landgraf Kolts for Defendant and Respondent.

In July 1991, plaintiff Winifred Armstrong underwent cataract surgery. Defendant Optical Radiation Corporation ("ORC") manufactured a product used during the surgery. In July 1992, Armstrong filed suit against ORC, alleging that its product had caused severe damage to her eye. She asserted causes of action for negligence, strict liability, and breach of warranty. ORC moved for summary judgment on the

ground that all of Armstrong's claims were preempted by federal law. The trial court granted the motion. We reverse.

BACKGROUND

In January 1991, Armstrong consulted with Dr. Richard Medof about a vision problem in her right eye. Based on Dr. Medof's advice, Armstrong decided to undergo surgery to have a cataract removed and to have an intraocular lens implanted.

On July 16, 1991, Dr. Medof performed the surgery at San Pedro Peninsula Hospital. During the procedure, he used Orcolon, a thick, transparent jelly-like fluid (commonly known as a viscoelastic) which is a surgical aid. Orcolon is manufactured by ORC.

On July 2, 1992, Armstrong filed this action against ORC, Dr. Medof, and the hospital, alleging that the use of Orcolon had caused severe damage to her right eye, including damage to the optic nerve.

In the first cause of action, for negligence, the complaint alleged that defendants had "carelessly . . . manufactured, designed, constructed, tested, inspected, distributed, provided, marketed, warranted and packaged [Orcolon] and knew or should have known that the same was capable of causing, and did in fact cause, personal injuries to the plaintiff while being used in a reasonably foreseeable manner and for which it was intended." Armstrong further alleged that defendants had failed to warn her of the potential dangers of Orcolon. She also claimed that the Orcolon used during her surgery had become contaminated through defendants' negligent failure to properly test, manufacture, and distribute the product.

The second cause of action, for strict liability, alleged that Orcolon contained design and manufacturing defects.

As a third cause of action, Armstrong alleged that defendants had expressly and impliedly warranted that Orcolon was fit for its intended use without causing physical injury but that, in fact, the product was defective, dangerous, and unsafe.

Finally, John Armstrong, Winifred's husband, asserted a cause of action for loss of consortium, in which he alleged that the injuries to his wife had damaged their relationship.[1]

In April 1994, ORC filed a motion for summary judgment, arguing that federal law barred all of plaintiffs' causes of action. More specifically, ORC maintained that because the federal Food and Drug Administration ("FDA") had approved the marketing of Orcolon, Armstrong's claims were preempted under the Medical Device Amendments of 1976 (21 U.S.C. § 360c et seq.) to the Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.). The parties fully briefed the matter. Following oral argument, the trial court granted the motion. Judgment was entered in favor of ORC in August 1994. The Armstrongs filed a timely notice of appeal.

DISCUSSION

The question of whether Armstrong's claims are preempted turns on the interpretation and application of the Medical Device Amendments of 1976 ("MDA" or the Act). "Statutory interpretation is a judicial function involving only questions of law. . . . On appeal we independently review the trial court's determination." (*Scott* v. *CIBA Vision Corp.* (1995) 38 Cal.App.4th 307, 313.) If Armstrong's claims are preempted, ORC "has established a complete defense and summary judgment was appropriate." (*Ibid.*)[2]

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[1] Because Mrs. Armstrong is the principal plaintiff, we use the name "Armstrong" to refer solely to her.

[2] To the extent there is a conflict in the evidence pertinent to the preemption issue, "[w]e must determine whether the facts as shown by the parties give rise to a triable issue of material fact. . . . In making this determination, the moving party's affidavits are strictly construed while those of the opposing party are liberally construed." (*Hanooka* v. *Pivko* (1994) 22 Cal.App.4th 1553, 1558, citation omitted; see also Code Civ. Proc., § 437c, subd. (*o*)(2).) We accept as undisputed facts only those portions of the moving party's evidence that are not contradicted by the opposing party's evidence. (*Kelleher* v. *Empresa Hondurena de Vapores, S.A.* (1976) 57
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A. General Provisions of the MDA

The MDA was enacted "'to assure the reasonable safety and effectiveness of medical devices intended for human use.'" (*Kennedy* v. *Collagen Corp.* (9th Cir. 1995) 67 F.3d 1453, 1455, cert. den. 116 S.Ct. 2579.) The Act classifies medical devices into three categories based on the risk they pose to the public. Class I devices (e.g., tongue depressors) pose little or no threat to public health and are subject only to minimal regulation by "general controls." (21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 860.3(c)(1) (1995).) Class II devices (e.g., oxygen masks) involve a higher risk of injury than class I devices. Although class II devices can be marketed without advance approval from the FDA, they must comply with performance regulations known as "special controls." (21 U.S.C. § 360(a)(1)(B); 21 C.F.R. § 860.3(c)(2) (1995).) Finally, a device falls into class III (e.g., a pacemaker) if either (1) the device "presents a potential unreasonable risk of illness or injury" or (2) "insufficient information exists to determine that the application of general controls [is] sufficient to provide reasonable assurance of the safety and effectiveness of the device, and [it] cannot be classified as a class II device because insufficient information exists to determine that .. . special controls . . . would provide reasonable assurance of its safety and effectiveness, and [the device] is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." (21 U.S.C. § 360c(a)(1)(C); see also 21 C.F.R. § 860.3(c)(3) (1995).)

Orcolon, an intraocular fluid, is a class III device. (21 C.F.R. § 886.4275 (1995).) As a new product, it had to receive premarket approval ("PMA") from the FDA before it could be marketed commercially. (See 21U.S.C. §§ 360c(a)(1)(C),

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Cal.App.3d 52, 56.) In other words, the facts alleged in the evidence of the party opposing summary judgment (and the reasonable inferences drawn therefrom) must be accepted as true. (*Zeilman* v. *County of Kern* (1985) 168 Cal.App.3d 1174, 1179, fn. 3.)

360e.) As a preliminary step in the approval process, ORC obtained an investigational device exemption under the MDA, which permitted it to investigate the safety and effectiveness of Orcolon by conducting clinical trials on humans. (See 21U.S.C. §§ 360e(a), 360j(g).) Having completed the investigational stage, ORC then applied for PMA.

"The PMA process requires a manufacturer to submit a detailed application to the FDA, including information pertaining to product specifications, intended use, manufacturing methods, and proposed labeling.. . . The FDA refers each application to a panel of qualified experts who prepare a report and recommendation accepting or rejecting the application. . . . Once the product receives PMA, the sponsor of the product may begin to market the product. Any subsequent changes in the product require submission of a PMA supplement application.. . . Furthermore, to ensure continued validity of the PMA, the product sponsor is required to submit post-approval reports at one-year intervals, identifying any changes in the device or any reports from clinical investigation or scientific literature concerning the device." (*Scott* v. *CIBA Vision Corp.*, *supra*, 38 Cal.App.4th at p. 315, citations omitted.)[3]

B. Preemption Under the MDA

The MDA contains an express preemption clause, title21, United States Code section 360k ("section 360k"), which provides: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement*—(1) which is *different from, or in addition to,* any *requirement applicable under [the Act]* to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the Act]." (21 U.S.C. § 360k(a), italics added.) As this provision

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[3] On March 29, 1991, the FDA approved ORC's application for premarket approval of Orcolon, thereby authorizing commercial use of the product.

makes clear, a state common law claim is preempted only if it imposes a "requirement" on a device which is "different from or in addition to" a federal "requirement" imposed under the MDA.[4]

Pursuant to statutory authority (21 U.S.C. §§ 360k(b), 371(a)), the FDA has promulgated regulations addressing the situations in which a state law requirement will be preempted. First, the regulations recognize that a state law requirement may take the form of a "statute, ordinance, regulation, or court decision." (21 C.F.R. § 808.1(b) (1995).) Thus, section 360k may preempt state common law claims. (*Scott* v. *CIBA Vision Corp., supra*, 38 Cal.App.4th at pp. 316-317.)

In addition, the regulations provide: "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements." (21 C.F.R. § 808.1(d) (1995).) However, section 360k "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code

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[4] Subsection (b) of section 360k authorizes the FDA to grant exemptions to state requirements that would otherwise be preempted under subsection (a). Subsection (b) states: "Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or (2) the requirement—(A) is required by compelling local conditions, and (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter." (21 U.S.C. §360k(b).)

(warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." (*Id.*, § 808.1(d)(1).) Nor is a state law requirement preempted if it is "equal to, or substantially identical to, requirements imposed by or under the act." (*Id.*, § 808.1(d)(2).) Finally, section 360k "[g]enerally . . . does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act." (*Id.*, § 808.1(d)(6)(ii).)

In *Medtronic, Inc.* v. *Lohr* (1996) 116 S.Ct. 2240, the Supreme Court gave a narrow reading to section 360k's preemptive scope. There, the plaintiff had suffered a "complete heart block" when her pacemaker failed, requiring emergency surgery. She filed suit against the manufacturer of the pacemaker, alleging causes of action under Florida law for negligence and strict liability. The negligence claim alleged a breach of the manufacturer's duty to use reasonable care in the design, manufacture, assembly, and sale of the product, including the failure to warn or properly instruct the plaintiff or her physicians of the tendency of the pacemaker to fail. (*Id.* at p. 2248.) The strict liability claim alleged that "the device was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale." (*Ibid.*) The manufacturer moved for summary judgment, and the district court granted the motion. The Eleventh Circuit Court of Appeals reversed in part and affirmed in part. It concluded that the plaintiff's negligent design claims were not preempted, but that the negligent manufacturing and failure-to-warn claims were preempted. Similarly, the court of appeals found that the strict liability claim was not preempted to the extent the plaintiff alleged an unreasonably dangerous design, but she could not assert the manufacturing or failure-to-warn claims under a strict liability theory. (*Id.* at pp. 2249-2250.)

The Supreme Court reversed the Eleventh Circuit in part, holding that none of the plaintiff's claims were preempted. (116 S.Ct. at p. 2259.) The high court

unanimously rejected the manufacturer's contention that section 360k preempts *all* state common law claims. (*Id.* at pp. 2251-2253 [plur. opn. of Stevens, J.], p. 2261 [conc. opn. of Breyer, J.], pp. 2263-2264 [conc. and dis. opn. of O'Connor, J.].) As Justice Stevens wrote in his plurality opinion: "[W]hen Congress enacted §360k, it was primarily concerned with the problem of specific, conflicting State statutes and regulations rather than the general duties enforced by common-law actions. . . . [Section] 360k refers to 'requirements' many times throughout its text. In each instance, the word is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries. . . . [¶] . . . [¶] The legislative history also confirms our understanding that § 360k simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." (*Id.* at pp. 2252-2253.) The plurality concluded that "given the critical importance of device-specificity in our (and the FDA's) construction of §360k, it is apparent that few, if any common-law duties have been preempted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.'" (*Id.* at p. 2259, quoting 21 C.F.R. § 808.1(d)(6)(ii) (1995).)

In examining the particular causes of action in *Medtronic*, a majority of the court agreed that section 360k did not act as a bar.[5] The court first held that the claims alleging defective manufacturing and labeling could proceed to the extent they were based on a violation of FDA regulations. As the court explained: "Nothing in §360k denies Florida the right to provide a traditional damages remedy for violations of

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[5] The majority consisted of the four members of the plurality (Justices Stevens, Kennedy, Souter, and Ginsburg) and Justice Breyer, who wrote a separate concurring opinion.

common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." (116 S.Ct. at p. 2255.)

The court then proceeded to reject the manufacturer's preemption defense in full, finding that the pertinent federal and state "requirements" were not sufficiently specific to the device at issue. After describing the requirements imposed by the MDA with respect to manufacturing and labeling and after reviewing the FDA regulations interpreting section 360k (see 116 S.Ct. at pp. 2256-2257), the court stated:

"Although we do not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted .. . , it is impossible to ignore its overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be 'with respect to' medical devices and 'different from, or in addition to' federal requirements. State requirements must also relate 'to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device,' and the regulations provide that state requirements of 'general applicability' are not pre-empted except where they have 'the effect of establishing a substantive requirement for a specific device.' Moreover, federal requirements must be 'applicable to the device' in question, and, according to the regulations, pre-empt state law only if

they are 'specific counterpart regulations' or 'specific' to a 'particular device.' The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.

"Such a comparison mandates a conclusion that the [plaintiff's] common-law claims are not pre-empted by the federal labeling and manufacturing requirements. The generality of those requirements make[s] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

"Similarly, the general state common-law requirements in this case were not specifically developed 'with respect to' medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the [plaintiff's] negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape pre-emption, not because the source of the duty is a

judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers. As a result, none of the [plaintiff's] claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA." (116 S.Ct. at pp. 2257-2258, fn. omitted.)[6]

In the wake of *Medtronic*, the United States Court of Appeals for the Ninth Circuit has held that section 360k does not preempt California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Saf. Code, §§25249.5-25249.13), better known as Proposition 65. (*Comm. of Dental Amalgam Mfrs. & Distribs.* v. *Stratton* (9th Cir. 1996) 92 F.3d 807.) Proposition 65 states in part: "No person in the course of

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[6] In a concurring and dissenting opinion written by Justice O'Connor, four members of the court agreed with the majority that the plaintiff's claims were not preempted to the extent they alleged a defective design or the violation of federal regulations. (116 S.Ct. at pp. 2263-2264.) However, unlike the majority, the dissent would have found that the manufacturing and labeling claims were preempted, stating: "Some if not all of the [plaintiff's] common-law claims regarding the manufacturing and labeling of [the pacemaker] would compel [the manufacturer] to comply with requirements different from or in addition to those required by the FDA. The FDA's Good Manufacturing Practice (GMP) regulations impose comprehensive requirements relating to every aspect of the device-manufacturing process, including a manufacturer's organization and personnel, buildings, equipment, component controls, production and process controls, packaging and labeling controls, holding, distribution, installation, device evaluation, and record keeping. . . . The [plaintiff's] common-law claims regarding manufacture would, if successful, impose state requirements 'different from, or in addition to' the GMP requirements, and are therefore pre-empted. In similar fashion, the [plaintiff's] failure-to-warn claim is pre-empted by the extensive labeling requirements imposed by the FDA. See, e.g., 21 C.F.R. § 801.109 (requiring labels to include such information as indications, effects, routes, methods, frequency and duration of administration, relevant hazards, contraindications, side effects, and precautions). These extensive federal manufacturing and labeling requirements are certainly applicable to the device manufactured by Medtronic. Section 360k(a) requires no more specificity than that for pre-emption of state common-law claims." (116 S.Ct. at p. 2264, conc. and dis. opn. of O'Connor, J.)

doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." (Health & Saf. Code, §25249.6.) This warning requirement is satisfied through "general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." (*Id.*, § 25249.11, subd. (f).)

In rejecting the argument that Proposition 65 imposes requirements different from those mandated by the MDA's manufacturing and labeling regulations, the Ninth Circuit stated: "Proposition 65 is a state law of general applicability which was not enacted 'with respect to' medical devices. Proposition 65 applies to all products and services that pose a health risk to the public. Except for identifying chemicals known to pose a health risk, Proposition 65 is not directed at any product or industry. . . . [¶] Thus, we hold that the consumer warning requirement under California's Proposition 65 is not 'specific' enough to trigger preemption because it is 'not the kind[] of requirement[] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.'" (92 F.3d at p. 813.)

With these principles in mind, we now turn to the causes of action in the case before us.[7]

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[7] Armstrong argues that, because ORC violated federal regulations and failed to comply with the conditions of approval of the PMA, the FDA's order of approval was invalid and, consequently, section 360k has no application in this case. We reject this contention for two reasons. First, Armstrong did not establish as a matter of law that ORC violated federal regulations or the conditions of approval. Second, even assuming that a PMA order automatically becomes invalid (without any action by the FDA) upon a manufacturer's violation of federal regulations or the conditions of approval, Armstrong did not establish *when* ORC violated those requirements to such an extent
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C. Application of Section 360k to Armstrong's Claims

Medtronic teaches that three factors must be present before section 360k will preempt a state common law claim: (1) a state requirement specifically developed with respect to medical devices (2) which is different from or in addition to (3) a federal requirement specific to a particular device. If any of these factors is absent, the state law claim is not preempted.

With respect to all of Armstrong's causes of action, ORC attempts to distinguish *Medtronic* on the ground that the device in that case, unlike Orcolon, had not received premarket approval. That is undoubtedly true. As the Supreme Court explained:

"Not all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement. First, Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices. The statute therefore includes a 'grandfathering' provision which allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA. . . . Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act also permits devices that are 'substantially equivalent' to pre-existing devices to avoid the PMA process.

"Although 'substantially equivalent' Class III devices may be marketed without the rigorous PMA review, such new devices, as well as all new Class I and Class II devices, are subject to the requirements of § 360(k). That section imposes a limited form of review on every manufacturer intending to market a new device by requiring it

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that the PMA became invalid. We therefore cannot determine whether the PMA was invalid before Armstrong's surgery.

to submit a 'premarket notification' to the FDA (the process is also known as a '§ 510(k) process,' after the number of the section in the original Act). If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis (at least until the FDA initiates the PMA process for the underlying pre-1976 device to which the new device is 'substantially equivalent'). The §510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. . . .

"Congress anticipated that the FDA would complete the PMA process for Class III devices relatively swiftly. But because of the substantial investment of time and energy necessary for the resolution of each PMA application, the ever-increasing numbers of medical devices, and internal administrative and resource difficulties, the FDA simply could not keep up with the rigorous PMA process. As a result, the § 510(k) premarket notification process became the means by which most new medical devices—including Class III devices—were approved for the market." (116 S.Ct. at p. 2247, citations and fn. omitted.)

Because the pacemaker in *Medtronic* had qualified for commercial use under section 501(k)'s "substantial equivalency" test, it was subject only to the MDA's *general* regulations on manufacturing and labeling. In contrast, Orcolon underwent the rigors of the PMA process, which required ORC to submit to the FDA specific information unique to Orcolon's design, manufacture, marketing, and distribution.[8]

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[8] The PMA application must contain: "(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective; (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device; (C) a full description of the methods used in, and the facilities and controls used for, the manufacture,
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The FDA approved Orcolon for commercial use based upon that information. (See 21 U.S.C. § 360e(d).) Once approved, "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." (21C.F.R. § 814.80 (1995).)

Put another way, in approving Orcolon through the PMA process, the FDA imposed federal requirements specific to that product which govern virtually every aspect of its production and sale. Consistent with this view, the court in *Scott* v. *CIBA Vision Corp.*, *supra*, 38 Cal.App.4th at pages 318-319, held that the PMA itself constitutes a "specific counterpart regulation" within the meaning of the FDA regulations governing the preemption of common law claims (21C.F.R. § 808.1(d) (1995)). (But see *Kennedy* v. *Collagen Corp.*, *supra*, 67 F.3d at pp. 1458-1460 [FDA approval of PMA application does not constitute a federal requirement specific to a particular device].)

Accordingly, in evaluating the effect of section 360k on Armstrong's claims, we recognize that there are pertinent federal requirements specific to Orcolon which dictate

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processing, and, when relevant, packing and installation of, such device; (D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard; (E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing; (F) specimens of the labeling proposed to be used for such device; and (G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require." (21U.S.C. § 360e(c)(1).)

its design, manufacture, marketing, labeling, packaging, and distribution. As stated, however, the existence of a device-specific federal requirement is not sufficient to preempt a state law claim. That is only one of the three necessary factors. We therefore examine Armstrong's claims to determine whether the remaining factors are present: (1) a state law requirement specifically developed with respect to medical devices and (2) a conflict between the state and federal requirements. (See *Kernats* v. *Smith Industries Medical Systems, Inc.* (Ill.App.Ct. 1996) 669 N.E.2d 1300, 1308-1310 [despite premarket approval of medical device, section360k did not preempt plaintiffs' claims of negligence, strict liability, or breach of warranty].)[9]

1. The Negligence Claim

The complaint alleges that ORC was negligent in designing, manufacturing, marketing, and distributing Orcolon. Armstrong further alleges that ORC failed to warn her (through her physician and the hospital) of Orcolon's potential dangers.

The negligence claim is not preempted for two reasons. First, as ORC acknowledges, it is subject to FDA regulations with respect to the functions and duties underlying Armstrong's claim (e.g., manufacturing, labeling). To the extent the negligence claim parallels federal requirements or is based on a violation of FDA regulations, it is not "different from, or in addition to" the duties mandated by federal law. (*Medtronic, Inc.* v. *Lohr*, *supra*, 116 S.Ct. at pp. 2255-2256; see also *Evraets* v. *Intermedics Intraocular, Inc.* (1994) 29 Cal.App.4th 779, 791-794.)[10] Second, the state

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[9] Our discussion is limited to the claims that Armstrong has expressly pleaded in the complaint. Given our reversal of the summary judgment, we decline to address the parties' dispute as to whether the complaint can be fairly read to include additional claims (e.g., fraud). This issue can be resolved in the trial court after remand, and, if necessary, Armstrong can move to amend the complaint.

[10] Technically, such a claim is one for negligence "per se" because liability is premised on the violation of a statute or regulation. (6Witkin, Summary of Cal. Law (9th ed. 1988) Torts, §§ 818-819, pp. 170-172; Prosser & Keeton, Torts (5th ed. 1984)
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law requirements imposed by the negligence claim (e.g., the duty of a manufacturer to avoid foreseeable dangers in making a product or to inform users of potentially dangerous products of the risks involved) "were not specifically developed 'with respect to' medical devices." (*Medtronic, Inc.* v. *Lohr, supra*, 116 S.Ct. at p. 2258.) Rather, they are "requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to [medical] devices." (21C.F.R. § 808.1(d)(1) (1995).) "These state requirements therefore escape pre-emption .. . because their generality leaves them outside the category of requirements that §360k envisioned to be 'with respect to' specific devices . . . ." (*Medtronic, Inc.* v. *Lohr, supra*, 116 S.Ct. at p. 2258; see also *Evraets* v. *Intermedics Intraocular, Inc., supra*, 29 Cal.App.4th at p. 793 [discussing preemption of failure-to-warn claims].)

2. The Strict Liability Claim

Armstrong alleges the existence of both a design defect and a manufacturing defect in her strict liability claim. Before reaching any question of federal preemption, however, we note that California law precludes strict liability for a *design* defect in a medical device. (*Hufft* v. *Horowitz* (1992) 4 Cal.App.4th 8, 13-20.) In the context of medical devices, design defects must be pursued under a negligence theory. (*Ibid*; see also *Brown* v. *Superior Court* (1988) 44 Cal.3d 1049, 1058-1059.) On the other hand, California law does permit strict liability for a *manufacturing* defect in a medical device.

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§ 36, pp. 229-231.) In any event, in moving for summary judgment, ORC did not prove as a matter of law that it complied with all FDA regulations or PMA requirements. To the contrary, the FDA apparently made findings in October 1991 that "Orcolon is unsafe for its intended use" and that medical device reports "were not filed in compliance with [medical device reporting] regulations and with conditions of approval of the PMA." (See 21 C.F.R. § 803.1(a) (1995) [requiring report to FDA if "one of [the manufacturer's] marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur"].)

(*Hufft* v. *Horowitz, supra,* 4 Cal.App.4th at p. 17.) We therefore examine whether that theory of liability survives preemption under section 360k.

As with Armstrong's negligence claim, her theory of strict liability as to a manufacturing defect is based on general principles of state tort law which were not specifically developed with respect to medical devices. Thus, it is not preempted. (See *Medtronic, Inc.* v. *Lohr, supra,* 116 S.Ct. at p. 2258; 21 C.F.R. § 808.1(d)(1) (1995).)[11]

Further, section 360k "does not preempt a State or local requirement prohibiting the manufacture of adulterated . . . devices" unless the prohibition would establish "a substantive requirement for a specific device" which conflicts with a federal requirement. (21 C.F.R. § 808.1(d)(6)(ii) (1995).) Armstrong's principal contention, as disclosed in the parties' briefs, is that ORC failed to follow the manufacturing protocol approved by the FDA, resulting in a manufacturing defect. Plainly, if the manufacturing defect was the result of an error ORC made when producing Orcolon for commercial use, and not the result of a defect inherent in the FDA-approved manufacturing protocol, Armstrong's claim will not impose a requirement on the manufacture of Orcolon that conflicts with any federal requirement. Indeed, the gist of Armstrong's claim is that ORC did not comply with federally imposed manufacturing requirements.[12]

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[11] For the same reason, section 360k does not preempt a failure-to-warn claim based on a strict liability theory. (See also *Comm. of Dental Amalgam Mfrs. & Distribs.* v. *Stratton, supra,* 92 F.3d at pp. 812-814 [no preemption of state requirement that certain harmful chemicals bear warnings].) Nor does California law preclude strict liability for a failure to warn. (*Carlin* v. *Superior Court* (1996) 13 Cal.4th 1104, 1108-1109.) However, it is unclear whether Armstrong has alleged a failure-to-warn claim under a strict liability theory. That issue can be resolved on remand. (See fn. 9, *ante*.)

[12] ORC attempted to establish as a matter of law that the alleged defect in Orcolon was inherent in the FDA-approved manufacturing protocol. Although ORC submitted a declaration from one of its scientists to that effect, other evidence pointed to a failure to follow the protocol. For instance, in a February 7, 1992 letter to the FDA,
(footnote continued on next page)

As the plurality opinion noted in *Medtronic*: "[N]owhere in the materials relating to the [MDA's] history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices. To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the [MDA], not the pre-emption provision . . . ." (116 S.Ct. at p. 2253.) Accordingly, section 360k does not preempt Armstrong's strict liability claim based on a manufacturing defect.[13]

3. Breach of Warranty Claim

Armstrong's warranty claim alleges that Orcolon was not fit for its intended use. As the FDA regulations provide, section 360k "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices (e.g., requirements such as general electrical codes, and *the Uniform Commercial Code (warranty of fitness)*)." (21 C.F.R. § 808.1(d)(1)

(footnote continued from previous page)
ORC stated: "All of the information collected to date supports the conclusion that this serious clinical experience was caused by mechanical blockage of the trabeculum by microgels (cross-linked insoluble particles of polyacrylamide). Further, ORC [has] described investigations evaluating all potential sources of the microgel contamination and [has] described pilot production runs *confirming that these microgels were not inherently formed by the manufacturing process*." (Italics added.) Similarly, in a "Dear Doctor" letter ORC sent to physicians, the company stated that "microgels are small, flat particles of insoluble cross-linked polyacrylamide *inadvertently introduced during preparation of the process equipment*. The gels contaminated *random* syringes of ORCOLON." (Italics added.)

[13] In *Evraets* v. *Intermedics Intraocular, Inc., supra*, 29 Cal.App.4th 779 and *Scott* v. *CIBA Vision Corp., supra*, 38 Cal.App.4th 307, the courts found that section 360k preempted negligence and strict liability claims. To the extent those cases are inconsistent with *Medtronic*, we decline to follow them.

(1995), quoted with approval in *Medtronic, supra*, 116 S.Ct. at p. 2257, fn. 18, italics added.) Armstrong's warranty claim therefore survives preemption.[14]

4. Mr. Armstrong's Loss of Consortium Claim

The trial court apparently disposed of Mr. Armstrong's loss of consortium claim on the theory that all of Mrs. Armstrong's claims were without merit. In light of our reinstatement of her claims, it follows that his claims must also be allowed to proceed.

DISPOSITION

The judgment is reversed. Appellants are entitled to costs on appeal.

CERTIFIED FOR PUBLICATION.

MASTERSON, J.

We concur:

SPENCER, P. J.

VOGEL (Miriam A.), J.

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[14] Since Armstrong can maintain a strict liability claim based on a manufacturing defect (see pt. C.2., *ante*), California law does not preclude her warranty claim (see *Hufft* v. *Horowitz, supra*, 4 Cal.App.4th at p. 24).